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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/355,220	10/06/1999	THOMAS HASLER	11002/002001	6146

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EXAMINER

GRASER, JENNIFER E

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 01/15/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
09/355,220

Applicant(s)
Hasler et al.

Examiner
Jennifer Graser

Art Unit
1645



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Election, 5/21/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above, claim(s) 15-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 7
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: _____

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DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I, claims 1-14, in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 15-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention.

Claim Objections

2. Claims 4, 6, 8 and 10-14 are objected to under 37 CFR 1.75© as being in improper form because **a multiple dependent claim cannot depend from another multiple dependent claim**. See MPEP § 608.01(n). Correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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Claim 7 is vague and indefinite due to the phrase "for example" because it is unclear whether the limitation following the phrase is part of the claimed invention. See MPEP 2173.05(d).

Claims 13 and 14 are vague and indefinite because it is unclear what is meant by the term "deep bed filter". The specification on page 5 recites that "deep bed filter" means a filter which in contrast to a membrane filter (2-dimensional) possesses a 3-dimensional structure (depth). The prior art refers to what Applicant has described as "deep bed filters" as "depth filters". It is unclear whether Applicants are intending to claim the use of these depth filters in their methods or if their "deep bed filters" are in some way different from the depth filters taught in the prior art. Clarification is requested.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gotschlich et al (J. Exp. Med., 1969, 129(1): 1349-1365).

The instant claims are drawn solely to the broad isolation of polysaccharides and do not include the removal of endotoxins as is described in the instant specification. Gotschlich et al disclose a method of isolating polysaccharides from *N.meningitidis* which comprises using a

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detergent, Cetavlon, to rapidly precipitate polysaccharides from whole cell culture. Next ethanol is added to the solution and the mixture is centrifuged. The precipitate is then washed again with ethanol, then twice with acetone to remove the detergent and alcohol. See pages 1350-1351.

7. Claims 1-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Rienstra et al (EP 0 407 037 A1).

Rienstra et al teach the isolation of polysaccharides from Gram-negative bacteria and the removal of endotoxin from the polysaccharides. The instant claims are drawn solely to the isolation of polysaccharides and do not involve the removal of endotoxins. The instant claims do not exclude the additional use of phenol or other more toxic materials. Steps (a)-(e) of instant claim 1 are taught by Rienstra et al..

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over in view of Gotschlich et al. or Schneerson et al (J.Exp. Med. 1980. 152:361-376) in view of Hou et al (J. Parenteral Science and Technology, 1990. 44(4): 204-209) and Lewis (US 5,589,591).

Gotschlich et al disclose a method of isolating polysaccharides from *N.meningitidis* which comprises using a detergent, Cetavlon, to rapidly precipitate polysaccharides from whole

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cell culture. Next ethanol is added to the solution and the mixture is centrifuged. The precipitate is then washed again with ethanol, then twice with acetone to remove the detergent and alcohol. See pages 1350-1351. Schneerson et al teach the isolation of polysaccharides from *H.influenzae* for use in immune compositions. The polysaccharides are isolated by using a detergent, Cetavlon, to rapidly precipitate polysaccharides from whole cell culture. Next ethanol is added to the solution and the mixture is centrifuged. The precipitate is then washed again with ethanol, then twice with acetone to remove the detergent and alcohol.

However, Schneerson and Gotschlich et al do not specifically teach the use of a polymer filter, deep bed filter, or depth filter, for the removal of endotoxins from the isolated polysaccharides.

Hou et al teach a method for removing endotoxins from bacterial polysaccharides using a depth filter. Hou et al teach that the removal of these endotoxins is important for pharmaceutical purposes. Hou teaches that filtration methods using ultra filtration membranes or depth filters are popular means of depyrogenating biological solutions. The reference teaches that the positively charged depth filter is an effective, economical and practical method for endotoxin removal from large volumes (see page 208). Lewis teaches that a raw material must be free of bacterial endotoxins if it is to be used as a parenteral product. Lewis teaches that gel permeation chromatography or ultrafiltration can be used to separate endotoxin and product when the endotoxin is bigger or smaller than the product. Lewis also teaches that in instances when

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positively charged depth filters cannot be used, such as when the negatively charged product has characteristics similar to endotoxin, ultrafiltration can be used instead.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to use a depth filter (deep bed filter) or ultrafiltration with a polymer filter to remove the endotoxins from the polysaccharides isolated by Gotschlich et al. or Schneerson because both Hou and Lewis teach that the endotoxins are highly toxic and must be removed from pharmaceutical products prior to use. Hou teaches that positively charged depth filter is an effective, economical and practical method for endotoxin removal from large volumes (see page 208), while Lewis teaches that in instances when positively charged depth filters cannot be used, such as when the negatively charged product has characteristics similar to endotoxin, ultrafiltration can be used instead.

Additionally, the concentrations recited in dependent claims 8-11 are result effective variables. It has long been settled to be no more than routine experimentation for one of ordinary skill in the art to discover an optimum value of a result effective variable. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum of workable ranges by routine experimentation." Application of Aller, 220 F.2d 454, 456, 105 USPQ 233, 235-236 (C.C.P.A. 1955). "No invention is involved in discovering optimum ranges of a process by routine experimentation." Id. at 458, 105 USPQ at 236-237. The "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art." Application of Boesch, 617 F.2d 272, 276, 205 USPQ 215, 218-219 (C.C.P.A. 1980).

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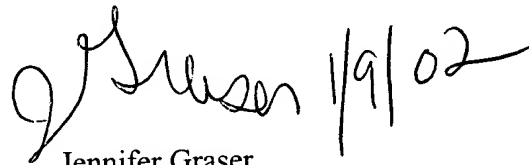
Since Applicant has not disclosed that the specific limitations recited in instant claims 8-11 are for any particular purpose or solve any stated problem and the prior art teaches that these concentrations often vary according to the specific sample being purified, absent unexpected results, it would have been obvious for one of ordinary skill to discover the optimum workable ranges of the methods disclosed by the prior art by normal optimization procedures.

10. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1645 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer E. Graser whose telephone number is (703) 308-1742. The examiner can normally be reached on Monday-Friday from 7:00 AM-4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jennifer Graser
Primary Examiner
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